PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Meloxicam 7.5 mg and 15 mg

Tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Meloxicam is and what it is used for
2. What you need to know before you take Meloxicam
3. How to take Meloxicam
4. Possible side effects
5. How to store Meloxicam
6. Contents of the pack and other information

1. What Meloxicam is and what it is used for

Meloxicam belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), which are used to reduce inflammation and pain in the joints and muscles.

Meloxicam is used for the:
- short-term treatment of flare ups of osteoarthrosis
- long-term treatment of
  - o rheumatoid arthritis
  - o ankylosing spondylitis (also known as Bechterew's Disease)

2. What you need to know before you take Meloxicam

Do not take Meloxicam:
- if you are allergic to meloxicam or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to aspirin, other anti-inflammatory medicines or other NSAIDs
- during the last 3 months of pregnancy
- if you are under 16 years of age
- if you have severely impaired liver function
- if you have ulcers or bleeding in your stomach or intestines
- if you have non-dialysed severe kidney failure
- if you have had any of the following signs after taking aspirin or other NSAIDs
  - o wheezing, chest tightness, breathlessness (asthma)
  - o nasal blockage due to swelling in the lining of your nose (nasal polyps)
  - o sudden skin or mucosal swelling, such as swelling around the eyes, face, lips, mouth or throat, possibly making breathing difficult (angioneurotic oedema)
- if after previous therapy with NSAIDs you have a history of;
  - o bleeding in your stomach or intestines
  - o holes (perforations) in your stomach or intestines
- if you have a history of ulcers or bleeding in your stomach or intestines (ulceration or bleeding occurring at least twice)
  - o if you have had recent bleeding in the brain (cerebrovascular bleeding)
  - o if you have severe heart failure

Warnings and precautions
Talk to your doctor before taking Meloxicam:
- If you have heart problems, had a previous stroke or think that you might be at risk of these conditions e.g. if you:
  - o have high blood pressure (hypertension)
  - o have high levels of sugar in the blood (diabetes mellitus)
  - o have high levels of cholesterol in the blood (hypercholesterolemia)
  - o are a smoker.

  As meloxicam may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.
- Meloxicam is not appropriate for immediate relief from acute pain.
- NSAIDs including meloxicam may mask the symptoms of an underlying infection. If you develop signs of infection, or if the symptoms worsen, you should contact your doctor. Do not use other NSAIDs at the same time as meloxicam. This is especially important if you are elderly, as the risk of side effects is higher.
- If you are a woman, meloxicam may make it more difficult to conceive. Tell your doctor if you are planning to become pregnant or are having problems conceiving. You should not take meloxicam if you are undergoing fertility treatment (see "Pregnancy, breast-feeding and fertility" section).
- The highest risk for occurrence of serious skin reactions is within the first month of treatment. If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of meloxicam, you must not be re-started on meloxicam at any time.
- If you have ever developed fixed drug eruption (a type of allergic reaction to a medicine causing skin lesions) after taking meloxicam or other oxicams (e.g. piroxicam).
- Your doctor may want to monitor your liver and kidneys during your treatment with meloxicam, in order to make sure they are working properly.
- It will be necessary to adjust the treatment of meloxicam in the following cases:
  - o history of inflammation of the gullet (oesophagitis), inflammation of the stomach (gastritis) or any other disease of the digestive tract e.g. ulcerative colitis or Crohn's disease
  - o high blood pressure
  - o older age
  - o heart, liver or kidney disease
  - o high levels of sugar in the blood (diabetes mellitus)
  - o reduced blood volume (hypervolemia) which may occur if you have a serious blood loss or burn, sugary or low fluid intake
  - o high potassium levels in the blood

Other medicines and Meloxicam
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even those obtained without a prescription. This includes herbal medicines.

In particular, tell your doctor if you are taking or have taken any of the following:
- anticoagulants, (medicines used to stop your blood clotting) such as warfarin, heparin, clopidogrel, dabigatran, apixaban and ticlopidine as meloxicam can increase their effect or you may be more likely to bleed
- other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as acetylsalicylic acid (aspirin) or medicines known as 'COX-2 inhibitors' such as celecoxib
- medicines which break down blood clots (thrombolytics)
- medicines to treat heart and kidney disease
- corticosteroids
- ciclosporin - used after organ transplants, or for severe skin conditions, rheumatoid arthritis or protein in the urine (nephrotic syndrome)
- any diuretic medicine ("water tablets"). Your doctor may want to monitor your kidney function if you are taking diuretics
- deferasirox, a medicine used to reduce levels of iron in the body
- lithium - used to treat mood disorders
- selective serotonin re-uptake inhibitors - used in the treatment of depression
- methotrexate - used to treat tumours or severe uncontrolled skin conditions and active rheumatoid arthritis
- pemetrexed, a medicine used to treat certain cancers. You may need to stop taking this medicine for at least 5 days before, during and 2 days after receiving pemetrexed
- cholestyramine - mainly used to lower cholesterol levels
- if you are a woman who uses an intrauterine contraceptive device (IUD), usually known as a coil
- other anti-inflammatory medicines or medicines which prevent or break down blood clots as taking these at the same time as meloxicam may increase the risk of stomach or intestinal ulcers, bleeding and damage to the gut and stomach lining.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
Do not take meloxicam if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.

You should not take meloxicam during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used.

If taken for more than a few days from 20 weeks of pregnancy onward, meloxicam can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Breast-feeding
This medicine should not be used if you are breast-feeding.

Fertility
This medicine is not recommended in women attempting to have a baby. The use of meloxicam may impair female fertility. In women who have difficulties in becoming pregnant or who are undergoing investigations of infertility, withdrawal of meloxicam should be considered.

Driving and using machines
Meloxicam may affect your ability to drive or use machines, due to possibility of dizziness, drowsiness and blurred vision as side effects. If you experience these effects, do not drive or operate machinery until the symptoms wear off.

Meloxicam contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Meloxicam contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Meloxicam

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Tablets should be swallowed with a glass of water or other liquid during a meal.

The scoreline is only to help break the tablet for ease of swallowing and not to divide into equal doses.

The recommended doses are as follows.

Flare-ups of osteoarthrosis
One 7.5 mg tablet a day, which may be increased (after consultation with your doctor) to 15 mg a day (two 7.5 mg tablets or one 15 mg tablet).

Rheumatoid arthritis
One 15 mg tablet per day (or two 7.5 mg tablets).
This may be reduced to one 7.5 mg tablet once a day.

Ankylosing spondylitis
One 15 mg tablet per day (or two 7.5 mg tablets).
This may be reduced to one 7.5 mg tablet once a day.

Do **not** exceed the maximum dose of 15 mg a day.

Elderly patients and patients with impaired kidney or liver function
For elderly patients, the recommended dose for long-term treatment of rheumatoid arthritis or ankylosing spondylitis is 7.5 mg per day.

Patients at high risk of side effects should start treatment with 7.5 mg a day.

If you have severe kidney disease and receive dialysis, the maximum dose of meloxicam should be 7.5 mg per day.

Use in children and adolescents
Meloxicam must not be given to children and adolescents under 16 years of age.

If you take more Meloxicam than you should
If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

Symptoms of overdose include: lethargy, drowsiness, nausea, vomiting and pain in the stomach. These symptoms are generally reversible. You may also suffer from bleeding of the stomach or intestines (gastrointestinal bleeding). Severe overdose, however, may result in serious adverse reactions (see section 4, "Possible Side Effects").

If you forget to take Meloxicam
Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Meloxicam and seek medical advice immediately if you develop:
Allergic reaction:
- skin reactions, such as itching (pruritis) blistering or peeling of the skin which can be severe (Steven-Johnson Syndrome and toxic epidermal necrosis) lesions of the soft tissue (mucosal lesions) or erythema multiforme. Erythema multiforme is a serious allergic reaction causing spots, red welts or purple or blistered area. It can affect the mouth, eyes and other moist body surfaces
- swelling of skin or mucosa, such as swelling around the eyes, face and lips, mouth or throat, possibly making breathing difficult, swollen ankles or legs (oedema of the lower limbs)
- shortness of breath or asthma attack
- inflammation of the liver (hepatitis); This can cause symptoms such as;
  o yellowing of the skin or whites of the eyes
  o pain in the abdomen
  o loss of appetite
- bleeding (causing tar-coloured stools) or vomiting of blood (haematemesis)
- ulceration of the digestive tract (causing abdominal pain), bleeding of the digestive tract (gastrointestinal bleeding), formation of ulcers or formation of a hole in the digestive tract (perforation). These may sometimes be severe and potentially fatal, especially in the elderly.

Very Common side effects (may affect more than 1 in 10 people)
- indigestion (dyspepsia)
- feeling sick (nausea) or being sick (vomiting)
- stomach ache (abdominal pain)
- constipation
- passing wind (flatulence)
- loose stool (diarrhoea)

Common side effects (may affect up to 1 in 10 people)
- headache

Uncommon side effects (may affect up to 1 in 100 people)
- dizziness (light-headedness)
- a feeling of dizziness or spinning (vertigo)
- somnolence (drowsiness)
- anaemia (which may make you feel tired and lacking in energy)
- increase in blood pressure
- flushing (temporary redness to face and neck)
- sodium and water retention
- increased potassium level (hyperkalaemia). This can lead to symptoms such as:
  o changes in the heartbeat (arrythmias) when you feel your heart is skipping beats or beating too fast
  o palpitations (when you feel your heart is beating more than usual)
  o muscle weakness
- eructation (belching)
- inflammation of the stomach (gastritis)
- inflammation of the mouth (stomatitis)
- immediate allergic reactions (hypersensitivity)
- abnormal liver function tests e.g. raised liver enzymes (like transaminases) or an increase of the bile pigment bilirubin (detected in a blood test)
- disturbance of laboratory tests investigating kidney (renal) function (e.g. raised creatinine or urea)

Rare side effects (may affect up to 1 in 1,000 people)
- changes in mood
- nightmares
- abnormal blood count including decrease in the white blood cell platelets. This may lead to increased risk of infections and symptoms such as increased bruising or nosebleeds
- ringing in the ears (tinnitus)
- feeling your heartbeat (palpitations)
- ulcers of the stomach or small intestines (peptic/gastroduodenal ulcers)
- inflammation of the gullet (oesophagitis)
- nettle rash (urticaria)
- visual disturbances including blurred vision
- inflammation of the eyeball or eyelids (conjunctivitis)
- inflammation of the large bowel (colitis)

Very rare side effects (may affect up to 1 in 10,000 people)
- acute failure of the kidneys (renal failure) in particular in patients with risk factors such as heart disease, diabetes or kidney disease
- complete loss of specific types of white blood cells (agranulocytosis), especially in patients who take meloxicam with other medicines that are potentially inhibitory, depressant or destructive to a component of the bone marrow (myelotoxic drugs).
  This can cause sudden fever, sore throats, infections.
- signs of a heart attack or stroke, which could be caused by a blood clot
  o signs of a heart attack include chest pain that may spread across the upper body or a feeling of tightness or heaviness in the chest, with sweating, nausea (feeling sick), vomiting (being sick) or dizziness
  o signs of a stroke include sudden weakness or numbness of the face, arm or leg, sudden severe headache, sudden changes in speech or confusion, sudden changes in balance, co-ordination or walking, or a loss of consciousness or seizure (fit)

Not known (frequency cannot be estimated from the available data)
- confusion
- disorientation
- heart failure (cardiac failure) has been reported in association with NSAID treatment
- inflammation of the pancreas (pancreatitis)
- sensitivity to sunlight (photosensitivity)
- a type of allergic reaction to a medicine causing skin lesions (fixed drug eruption), that usually recurs at the same site(s) on re-exposure to the medication
- female infertility, delayed ovulation

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Meloxicam

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton box/blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Meloxicam contains
Each tablet contains 7.5 mg or 15 mg of meloxicam.
The other ingredients are: maize starch, pregelatinised maize starch, colloidal anhydrous silica, sodium citrate, lactose monohydrate, microcrystalline cellulose, magnesium stearate.

What Meloxicam looks like and contents of the pack
Meloxicam 7.5 mg are yellow coloured, 7 mm, circular, flat, bevelled, uncoated tablets with a central scoreline on one side and plain on the other side.

Meloxicam 15 mg are yellow coloured, 10 mm, circular, flat, bevelled, uncoated tablets with a central scoreline on one side and plain on the other side

Meloxicam is available in blister packs of 20 or 30 tablets.
Not all pack sizes may be marketed.

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Till-GPAX-2

Product Name	Meloxicam 7.5/15 mg Tabs	**Sap code :**	TBA	**Reference Artwork**
Packaging Material	Package leaflet	**Reason of change :**	TW225523 (design)	
Size : Foil Width		**Country :**	UK	
Size : Foil Repeat Length		**Pack Size :**		
Size : Strip Size		**Barcode No. :**	NA	
Size : PI - Open Size	210 mm (w) x 380 mm (l)	**Pharmacode :**	TBA	
Size : Carton/Label		**No. of colours :**		
PM Style/Type :		**Min. Font Size :**	9 points (Reg text)	
Remark (If any) :				

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